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| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 10/816,702   | 04/01/2004  | James J. McCormick   | 559123-2            | 1168             |
| 23879  | 7590        | 02/24/2005           | EXAMINER            |                  |
| BRIAN M BERLINER, ESQ<br>O'MELVENY & MYERS, LLP<br>400 SOUTH HOPE STREET<br>LOS ANGELES, CA 90071-2899 |             |                      | PATEL, NIHIR B      |                  |
|  |             |                      | ART UNIT            | PAPER NUMBER     |
|  |             |                      | 3743                |                  |

DATE MAILED: 02/24/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                                      |  |  |
|------------------------------|--------------------------------------|--|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/816,702 | <b>Applicant(s)</b><br>MCCORMICK ET AL.  |  |
|                              | <b>Examiner</b><br>Nihir Patel       | <b>Art Unit</b><br>3743  |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on January 18<sup>th</sup>, 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) 10-23 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-9 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Election/Restrictions*

Applicant's election without traverse of species a (figures 1-4 on which claims 1-9 are readable) in the reply filed on January 18<sup>th</sup>, 2005 is acknowledged.

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Blachly, deceased et al. US Patent No. 4,270,531. Referring to claim 1, Blachly discloses an oropharyngeal airway and bite block assembly and method of use for closed pulmonary ventilation that comprises a substantially oval and bowed sheet of material 12 having an inner surface; an outer surface, a top portion, a bottom portion, an upper edge, and a lower edge (see figures 1-4); a central orifice 40 (see figures 2-4) through the approximate center of the substantially oval and bowed sheet of material 12; a tubular extension 20 having a proximal end, a distal end, and a conduit, wherein the conduit of the tubular extension at the proximal end of the tubular extension feeds into the central orifice 40 of the intraoral mouthpiece (see figures 1-4); and a reinforced collar 26 and 24 surrounding a portion of the tubular extension (see figures 1-4); and wherein the substantially oval and bowed sheet of material is configured to fit between gums and lips of a person (see figure 1 and column 4 lines 5-15), extending upward and downward substantially parallel to the

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gums and teeth of the person beyond the gum-line of the person, and extending posteriorly in the mouth of the person (see figure 1).

Referring to claim 3, Blachly discloses an apparatus wherein the top portion of the sheet of material is offset in an anterior-posterior plane with respect to the bottom portion of the intraoral mouthpiece (see figures 1-4).

Referring to claim 7, Blachly discloses an apparatus that further comprises an intraoral oropharyngeal airway having a proximal end and a distal end wherein the intraoral oropharyngeal airway provides an extension of the conduit of the tubular extension into the mouth of the person (see figures 1-4).

Referring to claim 9, Blachly discloses an apparatus wherein the intraoral mouthpiece further comprises a recess (see figure 3) on the inner surface of the sheet of material, the recess configured to mate with the proximal end of the intraoral oropharyngeal airway and wherein the intraoral oropharyngeal airway is positioned such that the proximal end of the intraoral oropharyngeal airway mates with the recess on the sheet of material (see figure 3).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 2 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Blachly US Patent No. 4,270,531 in view of Fitton US Patent No. 6,536,424. Referring to claim 2, Blachly discloses the applicant's invention as claimed with the exception of providing at least

one notch having an open side and an apex that is positioned so that the open side of the at least one notch is laterally centered on an edge of the substantially oval and bowed sheet of material and the apex is pointed toward the central orifice through the intraoral the intraoral mouthpiece. Fitton discloses an anatomical mouthpiece with retailing wings and method of use that does provide at least one notch 402 (see figure 5) having an open side and an apex that is positioned so that the open side of the at least one notch is laterally centered on an edge of the substantially oval and bowed sheet of material and the apex is pointed toward the central orifice through the intraoral the intraoral mouthpiece. Therefore it would have been obvious to modify Blachly's invention by providing at least one notch having an open side and an apex that is positioned so that the open side of the at least one notch is laterally centered on an edge of the substantially oval and bowed sheet of material and the apex is pointed toward the central orifice through the intraoral the intraoral mouthpiece as taught by Fitton in order to assist the patient in breathing.

Referring to claim 5, Blachly discloses the applicant's invention as claimed with the exception of providing substantially oval and bowed sheet of material that has substantially rounded upper and lower edges. Fitton discloses an anatomical mouthpiece with retailing wings and method of use that does provide substantially oval and bowed sheet of material that has substantially rounded upper and lower edges. Therefore it would have been obvious to modify Blachly's invention by providing substantially oval and bowed sheet of material that has substantially rounded upper and lower edges as taught by Fitton so that it fits comfortably in the patient's mouth.

Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Blachly et al. US Patent No. 4,270,531 in view of Kulick US Pub. No. 2002/0139375. Blachly discloses the

applicant's invention as claimed with the exception of providing an intraoral mouthpiece that comprises of plastic, rubber or silicone. Kulick discloses a method and apparatus for treatment of snoring, hypopnea and apnea that does provide an intraoral mouthpiece that comprises of plastic, rubber or silicone. Therefore it would have been obvious to modify Blachly's invention by providing an intraoral mouthpiece that comprises of plastic, rubber or silicone as taught by Kulick in order for the patient to have a stronger grip on the mouthpiece.

Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Blachly et al. US Patent No. 4,270,531 in view of Alfery US Patent No. 6,196,224. Blachly discloses the applicant's invention as claimed with the exception of providing an intraoral oropharyngeal airway has at least one row of notches towards the distal end of the intraoral oropharyngeal airway. Alfery discloses a perilaryngeal oral airway that does provide an intraoral oropharyngeal airway has at least one row of notches 390 (in a broad definition the fenestrations in Alfery define notches) towards the distal end of the intraoral oropharyngeal airway. Therefore it would have been obvious to modify Blachly's invention by providing an intraoral oropharyngeal airway has at least one row of notches towards the distal end of the intraoral oropharyngeal airways as taught by Alfery in order to assist the patient in breathing.

Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Blachly et al. US Patent No. 4,270,531 in view of Northway-Meyer US Patent No. 4,848,331. Blachly discloses the applicant's invention as claimed with the exception of providing a port extending through the tubular extension. Northway-Meyer discloses an apparatus and method for pulmonary ventilation of a patient concurrent with fiber-optic respiratory tract examination and tracheal intubation that does provide a port extending through the tubular extension. Therefore it would have been

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obvious to modify Blachly's invention by providing a port extending through the tubular extension as taught by Northway-Meyer in order to remove the exhaled air.

***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communication from the examiner should be directed to Nihir Patel whose telephone number is (571) 272-4803. The examiner can normally be reached on Monday-Friday from 7:30 am to 4:30 pm. If attempts to reach the examiner by telephone are unsuccessful the examiner supervisor Henry Bennett can be reached at (571) 272 4791.

NP  
February 11<sup>th</sup>, 2005



Henry Bennett  
Supervisory Patent Examiner  
Group 3700